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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,436	03/27/2001	Remi Delansome	01056	5099

23338 7590 12/06/2007

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EXAMINER	
DESAI, ANAND U	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
12/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/787,436	DELANSORNE ET AL.	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79,82,84-92,95 and 97-99* is/are pending in the application.

4a) Of the above claim(s) *85,86 and 88-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79,82,84,87,92,95 and 97-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to Amendment filed on August 10, 2007. Claims 79, 82, 84-92, 95, and 97-99 are currently pending. Claims 85, 86, and 88-91 have been withdrawn previously.

2. Claims 79, 82, 84, 87, 92, 95, 97, 98, and 99 are currently under examination.

Withdrawal of Rejections

3. The rejection of claims 79, 84, 87, 92, 97, 98, and 99 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn based on the amendment to the claims.

4. The rejection of claim 87 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the treatment of prostate cancer or benign prostatic hypertrophy, does not reasonably provide enablement for the prevention of prostate cancer or benign prostatic hypertrophy is withdrawn based on the amendment to the claims.

Pending Rejections

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 79, 82, 84, 87, 92, 95, 97, 98, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai et al. (U.S. 4,659,696) in view of Kurihara et al. (U.S. 5,051,402), Kano et al. (Journal of Inclusion Phenomena and Molecular Recognition in Chemistry 22: 285-298 (1995)), and Mehlem (US 2003/0162721 A1).

Hirai et al. teaches an LH-RH analog which is a polypeptide having the formula pGlu-His-Trp-Ser-Tyr-D-Ala-Leu-Arg-Pro-NHC_2H_5 (or leuprorelin) and 5 g of α-cyclodextrin (see col. 21, line 13-26). This peptide analog fits the formula of I defined in claims 79, 82, 92, and 95. Various cyclodextrins are taught, including tri-O-methylcyclodextrin (see column 4, lines 23-38). "Absorption enhancer" in claim 98 is

being interpreted as any excipient or pharmaceutical carrier that would increase the stability of the peptide. Thus, the excipient or pharmaceutical carriers used by Hirai et al. would meet this limitation. Hirai et al. does not disclose leuprorelin with the particular α-cyclodextrin derivatives.

Claim 92 recites limitations that refer to the intended use of the pharmaceutical formulation. Where it is possible that structural differences exist between the formulation of Hirai et al. and that of the present invention, there is nothing recited in the claims that distinguishes the present invention from the prior art.

The present method claims are directed to a method of orally administering an LH-RH analog with α-cyclodextrin derivative. Whereas *Hirai et al.*, teach the composition of the claims, non-oral administration routes are taught as the preferred method of administration.

The teachings of Kurihara et al. and Mehlem disclose peptides for oral administration are made up as capsules that may contain α-cyclodextrin derivatives. Kurihara et al. employs α-cyclodextrin derivatives for the oral administration of peptides, which is the problem that the present invention seeks to resolve (see col. 4, lines 17-60, and claims 1, 10, and 11). Mehlem describes the use of substituted cyclodextrins as carriers for peptides through an oral administration route. Kano et al. describes an added benefit to using α-cyclodextrin derivatives, because of a more flexible cavity for the inclusion of guests in α-cyclodextrin derivative, hexakis (2, 3, 6-tri-O-methyl)-α-cyclodextrin.

Thus, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to combine the LH-RH peptides of *Hirai et al.* with alpha-

cyclodextrin derivatives for the purposes of oral administration. A person of ordinary skill in the art would have been motivated to use the formulation for administration, as capsules comprising alpha-cyclodextrin derivatives have been used for the oral administration of peptides with some success because other peptides were used with alpha-cyclodextrin carriers. A person having ordinary skill in the art would have pursued the known potential solution of using an alpha-cyclodextrin derivative with a reasonable expectation of success. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

9. No claims are allowed.

10. All references have been cited in prior office actions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

October 29, 2007

AD
/Anand Desai/
Patent Examiner
Art Unit 1656